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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/790,342

03/01/2004

Lon S. Weiner

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9417

7590

08/10/2006

Jeffrey D. Shewchuk
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EXAMINER

CUMBERLEDGE, JERRY L

ART UNIT

PAPER NUMBER

3733

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/790,342

Applicant(s)

WEINER ET AL.

Examiner

Jerry Cumberledge

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ 08/22/05 ; 04/22/05
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____

DETAILED ACTION

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not state that the person making the oath or declaration has reviewed and understands the contents of the specification, including the claims, as amended by any amendment specifically referred to in the oath or declaration. The oath submitted states that the person making the oath understands the application, not the specification.

It does not identify the city and either state or foreign country of residence of each inventor. The residence information may be provided on either an application data sheet or supplemental oath or declaration.

Specification

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;

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- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

The abstract is too long. It should be reduced to 150 words or less.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Huebner (US Pat. 6,030,162).

Huebner discloses a device for connecting a bone fragment to an anchor bone for a healing duration and for extending out of the bone during the healing duration, the device having an elongated shaft (top Fig. 22, below) extending about a shaft axis and comprising: a bone exterior section/fragment exterior section (top Fig. 22, below) making up at least one third of a total length of the device (top Fig. 22, below); and a bone penetration section (top Fig. 22, below) extending distally from the bone exterior section, the bone penetration section comprising: a non-engaging fragment section (top Fig. 22, below); and a bone anchor section (top Fig. 22, below) located distally to the non-engaging fragment section, the bone anchor section having threads for engagement with the anchor bone (top Fig. 22, below), with a major diameter of the

threads being greater than a shaft diameter of the non-engaging fragment section (bottom Fig. 22, below); and a compression engagement on a distal end of the bone exterior section (Fig. 21, below), the compression engagement providing a shoulder (Fig. 21 below) extending at a substantial angle to the shaft axis for substantial contact with an exterior surface of the bone fragment. The bone exterior section is longer than the bone anchor section (top Fig. 22, below). The bone exterior section is more than 45% of a total length of the device (top Fig. 22, below). The bone exterior section has threads of a shallower pitch than the threads of the bone anchor section (top Fig. 22, below), and wherein the compression engagement is provided by a nut (Fig. 14 below) rotatably supported on the threads of the bone exterior section. The bone exterior section has external threads (Fig. 14 below) which mate with internal threads on the compression engagement (Fig. 14 below), and wherein the inside diameter of the internal threads on the compression engagement is smaller than the non-engaging fragment section such that the internal threads on the compression engagement cannot advance onto the non-engaging fragment section. The bone exterior section has threads of a different thread profile than the threads of the bone anchor section (top Fig. 22, below), and wherein the compression engagement is provided by a nut (Fig. 14 below) rotatably supported on the threads of the bone exterior section. The device is provided in a kit of a plurality of such devices each having a different length of non-engaging fragment section. The various embodiments found in the specification (Figs. 15-22) can be considered a kit. The compression engagement has a proximal side with a sloped profile to assist in removing the compression engagement after a healing

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duration through tissue (Fig. 21 below). A slope of the proximal side of the compression engagement increases from a gentle slope adjacent an outer diameter of the bone exterior section to a steeper slope distal to the gentle slope, thus providing a compression engagement of generally tear-drop cross-sectional shape (Fig. 21, below). The compression engagement is permanently fixed to the bone exterior section (Fig. 21, below). The shaft of the non-engaging fragment section is substantially smooth and cylindrical (top Fig. 22 below). The compression engagement is permanently fixed to the bone exterior section (Fig. 21 below). The threads on the bone anchor section are self-tapping distally for insertion (top Fig. 22, below). The threads on the bone anchor section are self-tapping proximally for removal (top Fig. 22, below). The compression engagement has a tear drop cross-sectional shape (Fig. 21 below), wherein the compression engagement is permanently affixed to the bone exterior section (Fig. 21 below), wherein the shaft of the non-engaging fragment section is substantially smooth and cylindrical (top Fig. 22, below), and wherein the threads on the bone anchor section are self-tapping distally for insertion (top Fig. 22, below) and self-tapping proximally (top Fig. 22, below) for removal. The bone anchor section ends in a distal drill tip (top Fig. 22, below) adapted for insertion in bone without pre-drilling. The shoulder of the compression engagement has a curvature (top Fig. 22, below) to contact the exterior surface of the bone fragment along the curvature. The fragment exterior major diameter is no greater than a mean of the anchor major diameter and the anchor minor diameter (bottom Fig. 22, below). The fragment major diameter can be made smaller than the average of the anchor major diameter and the anchor minor diameter (column 3, lines

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41-43 and column 5, lines 33-41). Huebner further discloses a rotation section (top Fig. 22, below). Huebner further discloses a pointed proximal drill tip (top Fig. 22, below).

The device of Huebner can perform a method of repairing a fractured bone, comprising: screwing a device through a bone fragment, the device comprising: an elongated shaft having a bone penetration section extending distally from a bone exterior section about a shaft axis, the bone penetration section being shorter than the bone exterior section, the bone penetration section including a fragment section and a bone anchor section located distally to the fragment section, the bone anchor section having threads with a major diameter of the threads being greater than a diameter of the fragment section, and a compression engagement on a distal end of the bone exterior section, the compression engagement providing a shoulder extending at a substantial angle to the shaft axis; and further screwing the device such that the bone anchor section advances into an anchor bone with the fragment section in the bone fragment. The device of Huebner can further perform a method with the bone anchor section advanced into the bone fragment but prior to the act of further screwing the device into the anchor bone, manipulating the bone exterior section to reposition or bias the bone fragment relative to the anchor bone. The device of Huebner can further perform a method including, after the manipulating act, holding the bone exterior section in a desired alignment during the further screwing act. After the further screwing act: the fragment section extends through the bone fragment without threaded engagement with the bone fragment; and the threads of the bone anchor section are in engagement with the anchor bone; and the compression engagement is in substantial contact with an

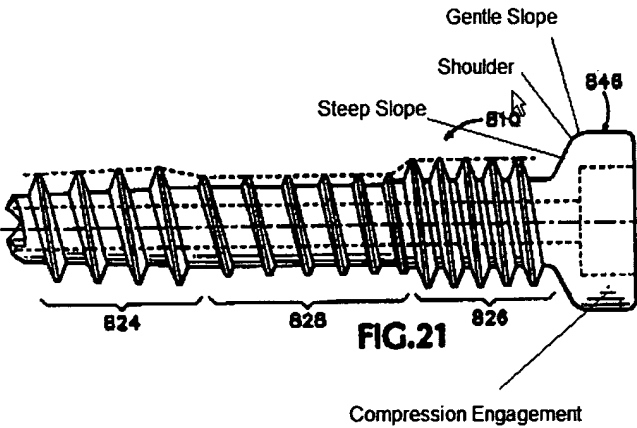
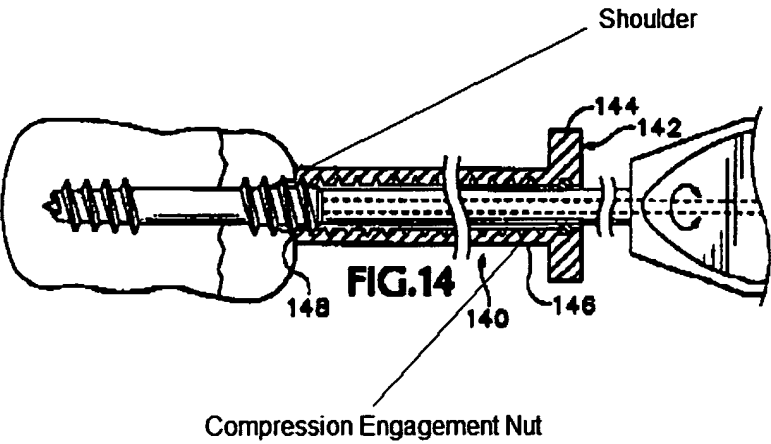
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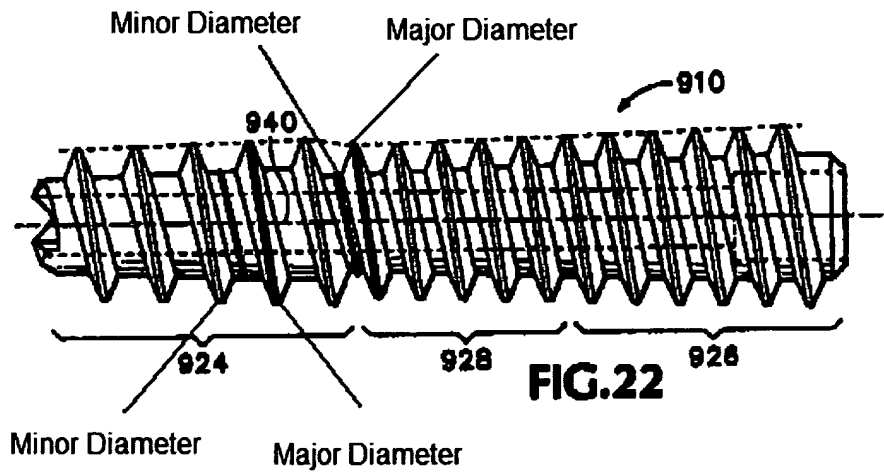
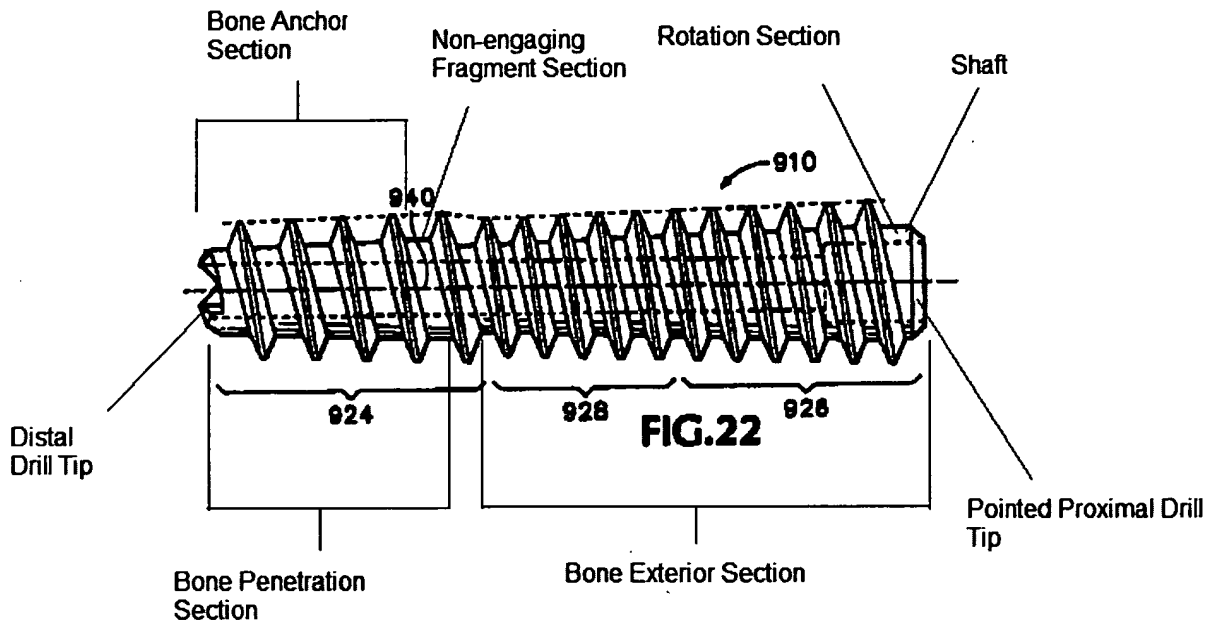
exterior surface of the bone fragment to bias the bone fragment toward the anchor bone. The device of Huebner can further perform a method including moving the compression engagement axially on the elongated shaft to position the compression engagement in an axial position to make substantial contact with an exterior surface of the bone fragment when the bone anchor section is advanced to a final position. The screwing act and the further screwing act occur in a reverse direction such that the device is inserted into the anchor bone prior to engaging the bone fragment, while the moving the compression engagement axially on the elongated shaft occurs in a forward direction, opposite to the direction the device was introduced to the bone. The device of Huebner can further perform a method including after the further screwing act, removing a portion of the bone exterior section so the bone exterior section does not extend as far outside the patient's tissue. The device of Huebner can further perform a method where the compression engagement has a proximal side with a sloped profile, and further comprising: after a healing duration, removing the compression engagement through tissue with the sloped profile on the proximal side of the compression engagement assisting in separating tissue. The device of Huebner can further perform a method further comprising monitoring torque applied during the further screwing act.

The device of Huebner can further perform a method of using a reverse-taper threaded compression device for placing a compression force on a fragment against an anchor substrate, the method comprising: advancing an anchor section disposed on a distal end of a shaft of the compression device into the anchor substrate, such that

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external threads on the anchor section engage the anchor substrate; advancing a compression engagement disposed on a fragment exterior section proximal to the anchor section relative to the shaft, such that the compression engagement makes contact with an exterior surface of the fragment to bias the fragment toward the anchor substrate; cutting off a portion of the fragment exterior section, the cut preventing the compression engagement from axially retracting on the shaft. The device of Huebner can further perform a method including removing the compression device from the anchor substrate by placing a reverse torque on the compression engagement.





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With regard to the statements of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over the device of Huebner, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993)*, *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985)*, *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982), *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970)*, and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 4-19, 21-23, and 29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over

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claims 2-5, 7-11, 14, 22, 24, 28, 29 of copending application # 10/300,078. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between claims 1-2, 4-19, 21-23, and 29 of the application and claims 2-5, 7-11, 14, 22, 24, 28, 29 of application # 10/300,078 lies in the fact that the application # 10/300,078 claims include many more elements and are thus much more specific. Thus the invention of claims 2-5, 7-11, 14, 22, 24, 28, 29 of application # 10/300,078 is in effect a "species" of the "generic" invention of claims 1-2, 4-19, 21-23, and 29. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 20 USPQ2d 2010 (Fed. Circ.1993). Since claims 1-2, 4-19, 21-23, and 29 are anticipated by claims 2-5, 7-11, 14, 22, 24, 28, 29 of application # 10/300,078, they are not patentably distinct from claims 2-5, 7-11, 14, 22, 24, 28, 29 of application # 10/300,078.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See attached PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER